Attorney Docket No.: 6535.200-US

USSN: 10/671,064

Filed: September 25, 2003 Inventor: Christensen et al. Via Facsimile No.: 571-273-8300

REMARKS/ARGUMENTS

Claims 1-34 are pending following entry of the above amendments to the claims. The amendment to claim 1 to recite "fermentation-derived product" finds support throughout the application.

REJECTION UNDER 35 U.S.C. 102 (b)

Claims 1-5, 11 and 17-20 are rejected as being anticipated by Mannweiler et al US Patent No 5,508,196.

Applicants respectfully traverse this rejection.

The claims as amended herein are directed to a process for purifying a <u>fermentation derived product</u> from a fermentation broth via microfiltration at a temperature within the range from 66 °C to 90 °C.

By comparison, Mannheim discloses that a continuous-operation bioengineering reactor comprises three stages, culture-medium sterilization, fermentation, and product finishing or product analysis (col. 1, lines 9-12) and describes a method directed towards the first stage (i.e., a method of continuously preparing a sterile culture medium) where one of the steps involves a transverse flow filtration module. Mannheim does not disclose use of microfiltration to purify a fermentation-derived product yet alone indicate that such a microfiltration process can be carried out at a temperature within the range from 66 °C to 90 °C. Accordingly, Mannheim does not anticipate the pending claims and withdrawal of this rejection is respectfully requested.

REJECTIONS UNDER 35 U.S.C. 103

A. Claims 1, 2, 5, 8-22 and 24 are rejected as obvious over Laustsen et al US Patent 6,582,606 in view of Weiss et al US Patent No 5,453,200.

The Laustsen patent is cited as disclosing microfiltration of fermentation products at a temperature of 65°C and the Weiss patent is cited as disclosing purification of

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proteins by membrane filtration and protein evaporation at 80°C, the latter alleged by the Examiner as suggesting that proteins are heat resistant at 80°C. The Examiner also alleges that Weiss teaches purification by microfiltration without activated carbon as conventional.

Applicants respectfully traverse this rejection.

It is well settled law that it is impermissible to use the inventor's disclosure as a "road map" for selecting and combining prior art disclosures. As the Federal Circuit stated in In re Fritch [972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992)] "[I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. ... This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention". Moreover, a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered.

Here, it is Applicants' position that the Examiner has not adhered to these principles.

The Laustsen patent teaches a microfiltration process comprising adding activated carbon to the product prior to or during the process where the process is carried out at a temperature between 25-65°C (see Abstract) and Weiss teaches that microfiltration is to be carried out at 40°C (col. 5, lines 1-18). Thus, the combined disclosures of Laustsen and Weiss regarding the temperature at which microfiltration of a fermentation product should be conducted, teach directly away from the temperature range disclosed in the present claims.

Nonetheless, the Examiner cites to the disclosure in Weiss of protein evaporation at 80°C (Weiss discloses that thermal concentration can be done with a primary steam temperature of 80°C and a secondary steam temperature of 35°C; see col. 6) as suggesting that one would conduct the microfiltration process of Laustsen at a temperature greater than 65°C. However, this assertion is completely contrary to what is actually taught in Weiss and Laustsen regarding the temperature at which microfiltration should be conducted

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and the Examiner has provided no basis for why one of ordinary skill in the art would nevertheless be motivated to apply the temperature of a thermal concentration step in Weiss to the microfiltration process of Laustsen.

Turning to the Examiner's assertion that the disclosure in Weiss that microfiltration may be conducted in the absence of activated carbon renders obvious the limitation of claim 2 (performing microfiltration in the absence of activated carbon), this rejection ignores the express teaching in the later filed Laustsen patent that use of activated carbon is critical to the microfiltration process disclosed therein. In particular, Laustsen states: "It has been surprisingly found that fouling can be efficiently minimized in microfiltration processes when activated carbon is added prior to or during the microfiltration step" (col. 2, lines 12-15). Thus, Laustsen expressly teaches away from performing microfiltration in the absence of activated carbon as recited in claim 2 [see In re Gurley, 7 F.3d 551, 553 31 USPQ2d 1130, 1131 (Fed. Cir. 1994), "in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant".

Accordingly, in view of the above remarks, Applicants respectfully request withdrawal of this rejection.

B. Claim 6 was rejected as obvious over Mannweiler in view of Rochilgo et al US Patent 5,143,630.

Applicants respectfully traverse this rejection.

As noted above, Mannheim discloses a method of continuously preparing a sterile culture medium where one of the steps involves a transverse flow filtration module. Mannheim neither teaches nor suggests the use of microfiltration at a temperature within the range from 66 °C to 90 °C to purify a fermentation derived product and Rochilgo does not cure this deficiency. Accordingly, withdrawal of this rejection is therefore respectfully requested

C. Claim 7 was rejected as obvious over Mannweiler in view of Husain et al US Patent 6,814,862 (actually 6,814,861).

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The teachings of Mannweiler are as above and Husain is directed to a method of purifying feedwater. Accordingly, as the combination of Mannweiler and Husain neither teaches nor suggests a process for purifying a fermentation-derived product via mcirofiltration, withdrawal of this rejection is respectfully requested.

Respectfully submitted,

Date: March 14, 2006

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23650